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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,863	10/30/2003	David E. Clapham	110313.135US3	1595

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EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,863	CLAPHAM ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/17/06*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, drawn to nucleic acids encoding a Catsper1 protein, vectors and transformed cells comprising the nucleic acids, and hybridizing nucleic acids; classified in class 435, subclass 69.1+.

II. Claims 26-28, drawn to a transgenic animal comprising nucleic acids encoding a Catsper1 protein, classified in class 800, subclass 8+.

III. Claims 29-32, drawn to a Catsper1 channel protein and preparations comprising, classified in class 530, subclass 350+.

IV. Claims 33-40 drawn to antibodies generated against Catsper1 and kits comprising antibodies, classified in class 530, subclass 387.1+.

V. Claims 94-96, drawn to methods of diagnosing an anti-Catsper1 antibody-mediated infertility, classified in class 530, subclass 387.1+.

VI. Claims 97-100, drawn to methods of treating an anti-Catsper1 antibody-mediated infertility, classified in class 530, subclass 387.1+.

VII. Claims 41, 43-49, 101, 103 and 105-107, drawn to a method of identifying agents that modulate the activity of the Catsper1 channel; classified in class 435, subclass 7.1+.

VIII. Claims 42, 43 and 46, drawn to a method of identifying agents that modulate expression of the Catsper1 channel; classified in class 536, subclass 23.5+.

IX. Claims 50-52, 54, 56-63, 65 and 67-70, drawn to a method of contraception in a male subject comprising administering a Catsper1 ligand; classification dependent on structure of agent.

X. Claims 53-60, 64-69, 71 and 110, drawn to a method of contraception in a female subject comprising administering a Catsper1 ligand; classification dependent on structure of agent.

XI. Claims 56, 67, 73 and 74, as reading on a method of inhibiting the expression of Catsper1 by administering antisense; classified in class 536, subclass 23.5+.

XII. Claims 72-74, drawn to a compound that decreases Catsper1 activity and compositions comprising; classification dependent on structure of agent.

XIII. Claims 75-88, drawn to a method of diagnosing a Catsper-related disorder caused by a mutated Catsper channel, classified in class 536, subclass 23.5+.

XIV. Claims 89-93, drawn to methods of in-vitro fertilization, classified in class 600, subclass 34.

XV. Claims 101-109 and 111, drawn to methods of conducting a drug discovery business, classified in class 705, subclasses 2 and 10.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I, II, III, IV and XII are independent and distinct, each from the

other, because they comprise products which possess characteristic differences in structure and function, and each has an independent utility that is distinct for each invention which cannot be exchanged. The nucleic acids of group I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The animal of Invention II can be used to study the physiological function of the gene of interest. The protein of Group III can be used to make an antibody or used therapeutically. The antibody of Group IV can be used to detect the polypeptide or can be used in treatment methods.

Invention I is also related to Invention II as product and process of use/making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide of Group I can be used for gene therapy or to produce the protein of Invention III.

Inventions I and V-VII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the polynucleotide is not used in antibody or ligand-binding methods of diagnosis or treatment.

Invention I is related to Inventions VIII and XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acids of Invention I are used in

cells and vectors to produce the Catsper protein. The nucleic acids and pharmaceuticals of Inventions VIII and XI are used to inhibit expression of Catsper.

Invention I and Inventions IX are directed to an unrelated product and process. In addition, Invention I and X are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the polynucleotide is not used in the methods of contraception.

Invention I is related to Invention XIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acids of Invention I are used in cells and vectors to produce the Catsper protein.

Invention I is related to Invention XIV as product and process of use/making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide of Group I can be used for gene therapy or to produce the protein of Invention III.

Inventions I and XV are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made

by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the polynucleotide is not used in the marketing or billing methods of running a drug-discovery business.

Invention II is related to Inventions V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the animal of Group II can be used to generate antibodies or to produce the protein of Invention III.

Inventions II and VII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the transgenic animal would not be used for in vitro methods of detecting ligands.

Inventions II and VIII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the transgenic animal would not be used for in vitro methods of modulating expression.

Invention II is related to Inventions IX and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the animal of Invention II can be used to determine the physiological function of Catsper1 as well as to generate antibodies.

Invention II may be related to Invention XI and XIII-XV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the animal of Invention II can be used to determine the physiological function of Catsper1 as well as to generate antibodies.

Invention III is related to Inventions V-VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the protein of Invention III can be used to generate antibodies.

Inventions III and VIII, IX, X, XI, XIII, XIV and XV are directed to an unrelated product and processes. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the protein would not be used or made by the methods listed.

Invention IV is related to Inventions V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the antibody of Invention IV can be used for in-situ localization of the Catsper protein.

Invention IV may be related to Invention VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the antibody of Invention IV can be used for in-situ localization or immunoprecipitation of the protein of interest.

Inventions IV and VIII, IX, X, XI, XIII, XIV, and XV are directed to an unrelated product and processes. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antibody would not be used in the methods listed.

Inventions V and XII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the ligand would not be used or made by the method listed.

Inventions XII and methods VI, VIII and XI are directed to an unrelated product and processes. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the ligand would not be used or made by the methods listed.

Inventions VII, IX and X are related to Invention XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05 (h)). In the instant case the ligand of Invention XII could also be used for in situ localization of the protein of interest.

Inventions V-XI and XIII-XV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are not used together, have different scopes and differing effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. The methods of Inventions V-XI and XIII-XV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. For example, in vitro binding assays using Catsper1 encompasses different subjects (cells versus multicellular organisms), different conditions, different protocols, personnel, and have differing chances of success than treatment methods, in vitro fertilization methods or business methods. Likewise, use of nucleic acids rather than polypeptides or ligands for treatment methods likewise encompasses different subjects, conditions, protocols and differing chances of success.

Because these inventions are distinct for the reasons given above, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Inventive Groups I through

XV. Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is

571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW
25 September 2006

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER